MAY 22 2002

510(k) SUMMARY

510(k) NUMBER:	K020577
SUBMITTED BY:	Applied Medical Resources Corporation 22872 Avenida Empresa Rancho Santa Margarita, CA-92688 (949) 713-8000
CONTACT PERSON:	Anil Bhalani Vice President of Regulatory Affairs and Clinical Programs
DATE OF PREPARATION:	May 10, 2002
NAME OF DEVICE:	Ureteral Catheter
CLASSIFICATION NAME:	Catheter, Ureteral, Gastro-Urology (Regulation Number 21CFR 876.5130, Urological catheter and accessories)
TRADE NAME:	Applied Ureteral Catheter
PREDICATE DEVICE:	Pigtail Ureteral Catheter (Ureteral Catheter, K923729), Cook Urological Inc., Spencer, IN.

INTENDED USE STATEMENT: The Applied Ureteral Catheter is indicated for use in the urinary tract where drainage or irrigation of the surgical site is desired. It may be used to introduce fluids such as radiopaque contrast media and saline solutions. The catheter is radiopaque and has a hydrophilic coating to facilitate insertion.

SUMMARY STATEMENT: The Applied Ureteral Catheter has a 5 Fr body, 70 cms long. It incorporates a retentive pigtail coil at one end. The coil aids in retention of the catheter in the renal pelvis during use. Drainage holes are arranged in a spiral pattern extending over the length of the coil to allow for fluid to be irrigated/aspirated through the catheter. The tip of coil has a smooth, atraumatic design for ease of passage through the urinary tract. A luer lock connector is attached at the other end, which may be connected to a drainage or irrigation system as desired. The catheter body is radiopaque and is coated with a hydrophilic coating, which is activated when wet.

The ureteral catheter is designed for placement over a guidewire of up to .038 inches in diameter that is pre-positioned through the urological tract. The catheter coil is temporarily straightened as it is slid over the guidewire. It is pushed up the urological tract until it is placed in a desired position. The luer lock hub is then connected to a source of irrigation or drainage fluid to attain the desired irrigation/aspiration of the urological site.

The ureteral catheter will be supplied in a tyvek/mylar peel pouch (one per pouch) and placed in an outer product carton (one to ten pouches per carton). The ureteral catheter may also be supplied along with a guidewire of up to .038 inches in diameter as a kit.

The Applied Ureteral Catheter is similar in function and performance to ureteral catheters currently marketed for the same application. The following tests were performed on the Applied Ureteral Catheter.

a. Irrigation Flow Rate
b. Drainage Flow Rate
c. Coil Retention Strength

Materials used in the manufacture of the Applied Ureteral Catheter were successfully tested to verify biocompatibility of the materials per ISO 10993-1.

Based on the above testing it was concluded that the Applied Ureteral Catheter is substantially equivalent to predicate devices and introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2002

Mr. Anil Bhalani
Vice President of Regulatory Affairs
and Clinical Programs
Applied Medical Resources Corp.
22872 Avenida Empresa
RANCHO SANTA MARGARITA CA 92688

Re: K020577
Trade/Device Name: Applied Ureteral Catheter with SL-6 Hydrophilic Coating
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EYB
Dated: February 19, 2002
Received: February 21, 2002

Dear Mr. Bhalani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Applied Ureteral Catheter "Indications for Use" as required.

510(k) Number: Not assigned

Device Name: Ureteral Stent

Indications for Use: The Applied Ureteral Catheter is indicated for use in the urinary tract where drainage or irrigation of the surgical site is desired. It may be used to introduce fluids such as radiopaque contrast media and saline solutions.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format -2-96)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020577